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EPA Expands Scope Of Sterilizers' Ethylene Oxide Reporting Under TRI

October 13, 2021

EPA is expanding the number of sterilization facilities currently required to report their emissions of the industrial solvent ethylene oxide (EtO) to the agency's Toxics Release Inventory (TRI), responding to environmentalists' pressure to expand reporting and eventually building the case for tougher air regulations for the chemical.

The agency Oct. 13 announced it has sent letters to 31 commercial sterilization facilities, informing them that they are under consideration for mandatory reporting of EtO emissions under the TRI. The plants have 30 days to respond and try to avoid the reporting requirement, for example if they have ceased their use of EtO.

But the new reporting requirement could bolster environmentalists' calls for the Biden administration to phase out use of EtO as a commercial sterilizer, often used to clean medical equipment.

In announcing the move, EPA officials sought to emphasize that the action is aimed in part at addressing widespread concerns, including from its Office of Inspector General (OIG), that the agency is taking seriously fears about the risks the chemical poses to exposed populations.

"EPA is committed to taking action to protect people from exposure to EtO, especially children, workers and residents in underserved and overburdened communities," said Assistant Administrator for the Office of Chemical Safety and Pollution Prevention Michal Freedhoff. "Requiring companies that use the largest amounts of EtO in this industry sector to report on this chemical will help inform EPA's future actions and ensure that communities have access to the best information available so they can take necessary action."

An EPA risk assessment in 2016 found EtO to be much more likely to cause cancer than previously thought, raising fears over emissions at facilities using the chemical around the country, and spurring tougher air regulation.

However, not all facilities are reporting to TRI, an inventory EPA uses as the basis for estimating risks to the community.

While TRI generally requires reporting of pollutants into air, water and land, some sterilization facilities have in the past been able to avoid reporting because they fell below reporting thresholds. For example, Sterigenics, a company with several facilities around the country, reported its EtO emissions to TRI from nine of its facilities in eight states prior to 2017, but then appeared to stop reporting. In 2016, the firm's Willowbrook, IL, facility reported 4,205 pounds of EtO air releases, down from 4,899 pounds in 2015.

The company's levels fell below the 10,000 pounds-per-year reporting threshold for "otherwise used" substances, which was already significantly lower than the 25,000 pounds-per-year threshold for manufacturing or processing of such substances.

But now EPA is proposing to subject the 31 facilities to TRI reporting mandates, because it believes "these 31 contract sterilization facilities use the highest amounts of EtO in the contract sterilization

facilities sector. The facilities are likely to exceed the 10,000 pounds per year 'otherwise used' TRI reporting threshold for EtO."

EPA also selected these facilities using authority in the Emergency Planning and Community Right-To-Know Act (EPCRA) that allows the agency to consider "other factors, including their proximity to a population center (e.g., the density of the population, including children, living near the facilities), their history of releases of ethylene oxide and ethylene glycol (e.g., past receipt of TRI reporting forms on ethylene oxide and ethylene glycol from these facilities), and other factors the Administrator determines are appropriate (e.g., proximity of the facilities to nearby schools and communities, especially those with potential environmental justice concerns)," the agency says.

Air Toxic Rules

The data gathered by expansion of the reporting requirements may eventually bolster the case for tougher air regulation of air toxics from sterilization facilities, as well as from other operations using EtO.

Environmental groups, and also the agency's Office of Inspector General, want EPA to tighten the existing air toxics rules governing the sector and others using the chemical, based on the 2016 assessment produced by the Integrated Risk Information System (IRIS) program.

However, it is unclear whether EPA will conduct a fresh health risk review for the sector, or rely instead only on a recurring, related technology review mechanism to require tougher emissions controls.

EPA plans to issue a proposed technology review for the sector later this year, and the agency has already been gathering data from industry for that purpose.

But new information gathered from the 31 facilities will apply to the 2022 TRI reporting year and not be due until mid-2023. It is therefore possible that the data will not inform the final version of commercial sterilizers rule, which EPA may finalize before the new TRI information is available.

EPA has also announced it will reconsider its Trump-era 2020 rule tightening the national emissions standards for hazardous air pollutants (NESHAP) for miscellaneous organic chemical manufacturing (MON), in light of an alternative risk assessment from Texas environmental regulators that finds the risks of EtO much lower than what IRIS found. That reconsideration rule appears likely to reaffirm the IRIS value and may further tighten the emissions limits, rather than loosening them as industry petitioners sought.

Meanwhile, EPA has been conducting a series of public outreach meetings with communities across the country located near EtO-emitting facilities, as part of the groundwork for further regulation of the chemical, as state-law legal actions spring up against various such plants around the country.

In one recent example, a New Mexico state court granted a preliminary injunction sought by the state to stop unplanned, or "fugitive," EtO releases from a sterilizer operated by Sterigenics in Santa Teresa, NM. The facility is one of the 31 plants now receiving letters warning of their addition to the TRI reporting list.

The state's enforcement effort, brought under public nuisance law, drew warnings from industry groups in an *amicus* brief that such court decisions will lead to a fractured regulatory landscape and undermine EPA's regulatory authority. However, EPA in its own brief sought to avoid involvement in the state law tort suit, downplaying the implications for the agency.